

July 8, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.93

Subject: Supplemental Assay Methods

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team

I. PURPOSE

The purpose of this memorandum is to present a current list of Supplemental Assay Methods (SAMs) which describe procedures, methods, and techniques used by the Center for Veterinary Biologics-Laboratory (CVB-L) for official assays of biological products according to 9 CFR 113.2(a).

II. CANCELLATION

This memorandum cancels Veterinary Biologics Memorandum No. 700.4 dated May 1, 1995, and the Listing of Supplemental Assay Methods dated May 1995.

III. APPLICATION

A. SAMs contain detailed instructions for conducting officially required tests. They do not supersede the requirements in the 9 CFR or those in filed Outlines of Production specifically requiring alternative procedures for the licensee or CVB-L.

B. CVB-L must follow SAMs. Revised SAMs must be issued before implementation by CVB.

IV. IDENTIFICATION OF SAMs

A. CVB-L will utilize a standardized title page format on all SAMs which includes the testing protocol heading, the descriptive title of the document, the date of the most recent version, the number, the standard requirement to which it applies, and the name of a person who has agreed to act as primary contact for comments and questions about the document.

B. Reference to these Supplemental Assay Methods should be made by the letters "SAM" and the applicable number.

C. CVB will number revisions of SAMs the same as the original and show the new date of issuance with the date of the one being superseded.

V. PREPARATION AND DISTRIBUTION

CVB will prepare and distribute SAMs. Initial distribution will be made electronically or by hardcopy to licensees, permittees, applicants, and appropriate Veterinary Services personnel. You may obtain additional copies by accessing the CVB home page at <http://www.aphis.usda.gov/vs/cvb>, or by sending a request to the CVB-L, 1800 Dayton Avenue, P.O. Box 844, Ames, Iowa 50010.

VI. AVAILABILITY

CVB will periodically issue notices of the addition, revision, or deletion of SAMs. CVB will maintain a current listing of SAMs on the CVB home page.

/s/ Alfonso Torres

Alfonso Torres
Deputy Administrator
Veterinary Services

Enclosure

APHIS:VS:CVB-LPD:EVEagly:hm:734-8245:6-21-99:I:\...\OS\13-033199

LISTING OF SUPPLEMENTAL ASSAY METHODS

July 1999

100 Series

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|-----|--|-------------------|
| 101 | Supplemental Assay Method for Titration of Bovine Virus Diarrhea Virus in Vaccines | September 1, 1981 |
| 102 | Supplemental Assay Method for Titration of Parainfluenza-3 Virus in Vaccines | January 1982 |
| 104 | Supplemental Assay Method for Isolation of Parainfluenza-3 Virus from Nasal Secretions | July 29, 1983 |
| 105 | Supplemental Assay Method for Titration of Bovine Rhinotracheitis Virus in Vaccines | May 1, 1982 |
| 107 | Supplemental Assay Method for Titration of Neutralizing Antibody (Constant Serum - Varying Virus Method) | June 14, 1971 |
| 108 | Supplemental Assay Method for Examination of Bovine Respiratory Disease Vaccines for Extraneous Bovine Virus Diarrhea Virus | November 1, 1987 |
| 109 | Supplemental Assay Method for Titration of Infectious Bovine Rhinotracheitis Neutralizing Antibody by a Virus Plaque Method | April 10, 1985 |
| 110 | Supplemental Assay Method for Titration of Serum for Eastern and Western Equine Encephalomyelitis Antibody Content by the Plaque Reduction Neutralization Method | February 17, 1998 |

- 111 Supplemental Assay Method for Titration of Infectious Bovine Rhinotracheitis Virus Neutralizing Antibody (Constant Virus - Varying Serum Method)
August 19, 1983
- 112 Supplemental Assay Method for Titration of Bovine Virus Diarrhea Neutralizing Antibody (Constant Virus - Varying Serum Method)
1984
- 113 Supplemental Assay Method for Titration of Parainfluenza-3 Neutralizing Antibody (Constant Virus - Varying Serum Method)
August 19, 1983
- 114 Supplemental Assay Method for Titration of Porcine Transmissible Gastroenteritis Virus (Approved Pending Standard Requirement)
November 16, 1998
- 115 Supplemental Assay Method for Titration of Bovine Virus Diarrhea Neutralizing Antibody (Constant Serum - Varying Virus Method)
June 1985
- 116 Supplemental Assay Method for Phenotypic Examination of Pseudorabies Virus for Thymidine Kinase Activity by a Plaque Selection Method
November 1, 1987 (DRAFT)
- 117 Supplemental Assay Method for Titration of Pseudorabies Virus Neutralizing Antibody (Constant Virus - Varying Serum Method)
August 3, 1998
- 118 Supplemental Assay Method for Titration of Pseudorabies Virus in Vaccines
October 27, 1998
- 120 Supplemental Assay Method for the *In Vitro* Potency Assay of Bovine Respiratory Viruses in Killed Vaccines
November 1, 1991 (DRAFT)

- 121 Supplemental Assay Method for Titration of Porcine Rotavirus in
Vaccines
April 1, 1992 (DRAFT)
- 122 Supplemental Assay Method for Titration of Porcine Rotavirus Antibody
(Constant Virus - Varying Serum Method)
April 1, 1992 (DRAFT)
- 123 Supplemental Assay Method for Pseudorabies Virus Challenge Test in
Swine
March 2, 1999
- 124 Supplemental Assay Method for Conducting the Hemagglutination
Inhibition Assay for Equine Influenza Antibody
October 28, 1994 (DRAFT)
- 125 Supplemental Assay Method for Titration of Bovine Rotavirus in
Vaccines
September 1, 1995 (DRAFT)
- 126 Supplemental Assay Method for Titration of Bovine Rotavirus Antibody
September 1, 1995 (DRAFT)
- 200 Series
- 200 Supplemental Assay Method for Potency Testing Products Containing
Clostridium chauvoei Antigen
April 15, 1998
- 201 Supplemental Assay Method for Potency Testing *Clostridium perfringens*
Type C Beta Antigen
April 26, 1999
- 2022 Supplemental Assay Method for Potency Testing *Clostridium perfringens*
Type C Antitoxins
October 29, 1998

- 203 Supplemental Assay Method for Potency Testing *Clostridium perfringens*
 Type D Epsilon Antigen
 April 26, 1999
- 204 Supplemental Assay Method for Potency Testing *Clostridium perfringens*
 Type D Antitoxins
 January 23, 1999
- 206 Supplemental Assay Method for Potency Testing of Tetanus Antitoxin
 May 1, 1987
- 207 Supplemental Assay Method for Potency Testing *Clostridium novyi* Type
 B Antigen
 March 4, 1999
- 209 Supplemental Assay Method for Potency Testing Products Containing
 Clostridium haemolyticum Antigen
 February 16, 1999
- 212 Supplemental Assay Method for Potency Testing *Clostridium sordellii*
 Antigen
 August 25, 1998
- 213 Supplemental Assay Method for Potency Testing of *Clostridium*
 botulinum Type C Bacterin-Toxoids
 September 23, 1980
- 214 Supplemental Assay Method for Immunogenicity and Spore Count Testing
 of Anthrax Spore Vaccine-Nonencapsulated
 February 16, 1999
- 216 Supplemental Assay Method for Potency Testing of Commercial Equine
 Tetanus Antitoxin by CELISA
 May 28, 1999 (DRAFT)
- 217 Supplemental Assay Method for Potency Testing of Tetanus Toxoid by
 ELISA
 February 8, 1999 (DRAFT)

221 Supplemental Assay Method for Identity Testing Clostridial Master Seeds
January 26, 1999 (DRAFT)

300 Series

302 Supplemental Assay Method for Titration of Canine Distemper Virus in
Cell Culture
April 30, 1999

303 Supplemental Assay Method for Titration of Canine Distemper Virus in
Chicken Embryos
January 25, 1971

304 Supplemental Assay Method for Titration of Infectious Canine Hepatitis
Virus in Primary Canine Kidney Cell Culture
November 1, 1984

305 Supplemental Assay Method for the Titration of Feline Panleukopenia
Virus in Cell Culture
July 1, 1999

306 Supplemental Assay Method for Titration of Feline Calicivirus in Cell
Culture
December 16, 1998

307 Supplemental Assay Method for Titration of Feline Rhinotracheitis Virus
in Cell Culture
December 16, 1998

308 Supplemental Assay Method for Potency Testing of Inactivated Rabies
Vaccine in Mice Using the National Institutes of Health Test
March 12, 1999 (DRAFT)

309 Supplemental Assay Method for the Titration of Canine Parainfluenza
Virus
June 1, 1985

- 310 Supplemental Assay Method for Scoring Feline Calicivirus in Cats
Following Challenge
 March 5, 1999
- 311 Supplemental Assay Method for Scoring Feline Rhinotracheitis Virus in
Cats Following Challenge
 March 5, 1999
- 312 Supplemental Assay Method for Detection of Cytopathogenic Agents
 June 1, 1985
- 313 Supplemental Assay Method for the Detection of Hemadsorbing Agents
 June 1, 1985
- 314 Supplemental Assay Method for Detection of Extraneous Viruses by the
Fluorescent Antibody Test
 June 1, 1985
- 315 Supplemental Assay Method for the Detection of Serum Neutralizing
Antibodies to Rabies Virus Using the Rapid Fluorescent Focus Inhibition
Test (RFFIT)
 March 1, 1986
- 316 Supplemental Assay Method for Titration of Canine Parvovirus in Cell
Culture
 August 1, 1987
- 317 Supplemental Assay Method for Titration of Canine Adenovirus in Canine
Kidney Cell Culture
 August 1, 1987
- 318 Supplemental Assay Method for Evaluation by the Relative Potency
Method of *In Vitro* Enzyme Immunoassays Used in Testing of Veterinary
Vaccines
 March 19, 1998

- 319 Supplemental Assay Method for Titration of Feline *Chlamydia psittaci* in Cell Culture
July 27, 1995 (DRAFT)
- 320 Supplemental Assay Method for Titration of Feline *Chlamydia psittaci* in Chicken Embryos
July 28, 1995 (DRAFT)
- 321 Supplemental Assay Method for Quantitating gp70 Antigen of Feline Leukemia Virus Veterinary Vaccines
April 1, 1994 (DRAFT)
- 322 Supplemental Assay Method for Determination of the Specific Viral Antigen Content in Inactivated Canine Coronavirus Vaccines
March 22, 1999 (DRAFT)
- 323 Supplemental Assay Method for Titration of Canine Distemper Virus in Vero Cell Culture
May 7, 1999 (DRAFT)

400 Series

- 405 Supplemental Assay Method for Detecting Lymphoid Leukosis Biocontamination by the COFAL Test
July 1, 1973
- 406 Supplemental Assay Method for Titration of Herpesvirus of Turkeys (Strain FC-126) or Chicken Herpesvirus (Strain SB-1)
October 29, 1998
- 407 Supplemental Assay Method for Titration of Herpesvirus of Turkeys (Strain FC-126), Lyophilized
October 29, 1998
- 408 Supplemental Assay Method for Titrating Tissue Culture Adapted Vaccine Strains of Infectious Bursal Disease Virus
December 16, 1998

409 Supplemental Assay Method for Titrating the Fractions of Combination
Avian Encephalomyelitis/Pox Vaccine
December 16, 1998

411 Supplemental Assay Method for the Titration of Newcastle Disease
Vaccine, Infectious Bronchitis Vaccine, and Combination Newcastle
Disease-Infectious Bronchitis Vaccine in Chicken Embryos
October 29, 1998

500 Series

504 Supplemental Assay Method for the Manual Determination of Protein
Content of Veterinary Biologics (Biuret)
April 24, 1997

509 Supplemental Assay Method for the Mikrozone-Electrophoretic
Separation of Blood Fractions Used in Veterinary Biologics
April 24, 1997

510 Supplemental Assay Method for the Manual Determination of
Formaldehyde in Veterinary Biologics (Schiff Test)
May 5, 1997

512 Supplemental Assay Method for the Examination of Bovine Nutrient
Serum for Extraneous Bovine Virus Diarrhea Virus Contamination
April 12, 1973

513 Supplemental Assay Method for the Determination of Protein and Phenol
in PPD (Purified Protein Derivative Produced From Cultures of
Mycobacterium bovis Strain AN-5) Bovis Tuberculin
December 10, 1998

514 Supplemental Assay Method for the Determination of Hydrogen Ion
Concentration, Total Nitrogen, Trichloroacetic Acid Precipitable
Nitrogen, and Phenol in Intradermic (Filtrate produced from cultures of
Pn, C, and Dt strains of *Mycobacterium tuberculosis*) Tuberculin
February 21, 1996

600 Series

- 600 Supplemental Assay Method for Purity, Potency, and Dissociation of
 Brucella Abortus Vaccine, Strain 19
 July 16, 1974
- 601 Supplemental Assay Method for Potency Testing of Erysipelas Antiserum
 in Mice
 March 19, 1999
- 602 Supplemental Assay Method for Evaluation of Salmonella Pullorum
 Antigens
 April 11, 1986
- 603 Supplemental Assay Method for Potency Testing of Fowl Cholera
 (*Pasteurella multocida*) Bacterins, Type 3
 March 18, 1999
- 604 Supplemental Assay Method for the Evaluation of Koch's Old Tuberculin
 March 22, 1999
- 605 Supplemental Assay Method for Potency Testing of Erysipelas Bacterins
 in Swine
 May 25, 1982
- 606 Supplemental Assay Method for Potency Testing of Erysipelas Vaccines
 in Swine
 May 20, 1982
- 607 Supplemental Assay Method for Potency Testing of Fowl Cholera
 (*Pasteurella multocida*) Bacterins, Type 1
 March 17, 1999
- 608 Supplemental Assay Method for Potency Assay of *Leptospira*
 interrogans Serovar *pomona* Bacterins
 July 1, 1999

- 609 Supplemental Assay Method for Potency Assay of *Leptospira interrogans* Serovar *canicola* Bacterins
July 1, 1999
- 610 Supplemental Assay Method for Potency Assay of *Leptospira interrogans* Serovar *icterohaemorrhagiae* Bacterins
July 1, 1999
- 611 Supplemental Assay Method for Potency Testing of Erysipelas Bacterins in Mice
May 20, 1982
- 612 Supplemental Assay Method for Bacterial Count of Erysipelothrix Rhusiopathiae Vaccines
March 1, 1986
- 613 Supplemental Assay Method for Potency Testing of Erysipelothrix Rhusiopathiae Bacterins
April 7, 1994 (DRAFT)
- 617 Supplemental Assay Method for Potency Assay of *Leptospira Interrogans* Serovar *grippotyphosa* Bacterins
July 1, 1999
- 620 Supplemental Assay Method for Potency Testing Enterotoxigenic (K99 Pilus) *Escherichia coli* Bacterins
April 28, 1999
- 621 Supplemental Assay Method for Potency Testing Enterotoxigenic (K88 Pilus) *Escherichia coli* Bacterins
April 28, 1999
- 622 Supplemental Assay Method for Potency Testing Enterotoxigenic (987P Pilus) *Escherichia coli* Bacterins
April 30, 1999

- 623 Supplemental Assay Method for Potency Testing Enterotoxigenic (F41 Pilus) *Escherichia coli* Bacterins
April 30, 1999
- 630 Supplemental Assay Method for Potency Testing of Fowl Cholera (*Pasteurella multocida*) Bacterins, Type 4
February 6, 1999 (DRAFT)
- 631 Supplemental Assay Method for Potency Testing of *Salmonella typhimurium* Bacterins
June 14, 1999 (DRAFT)
- 632 Supplemental Assay Method for Potency Testing of *Salmonella choleraesuis* Bacterins
June 14, 1999 (DRAFT)
- 633 Supplemental Assay Method for Potency Testing of *Salmonella dublin* Bacterins
June 14, 1999 (DRAFT)
- 634 Supplemental Assay Method for Potency Testing of *Pasteurella multocida* Bacterins of Bovine Origin
June 14, 1999 (DRAFT)
- 635 Supplemental Assay Method for Potency Testing of *Pasteurella multocida* Bacterins of Porcine Origin
May 28, 1999 (DRAFT)
- 636 Supplemental Assay Method for the Evaluation of Tuberculin Purified Protein Derivative (PPD)
July 1, 1999 (DRAFT)
- 800 Series
- 801 Supplemental Assay Method for Examination of Porcine Cells for Porcine Parvovirus Contamination
September 16, 1983

802 Supplemental Assay Method for Identification of Vaccine Strains of
Newcastle Disease Virus
December 16, 1998

803 Supplemental Assay Method for Examination of Trypsin Solutions for
Porcine Parvovirus Contamination
October 14, 1983

900 Series

900 Supplemental Assay Method for Testing Growth Promoting Qualities of
Fluid Thioglycollate Medium and Soybean-Casein Digest Medium using
Bacillus subtilis Spores and *Candida krusei* as the Indicator Organisms
March 22, 1999

901 Supplemental Assay Method for Testing Growth-Promoting Qualities of
Fluid Thioglycollate Medium with Beef Extract Using *Clostridium*
chauvoei Spores as the Indicator Organism
March 3, 1999

902 Supplemental Assay Method for Testing Growth Promoting Qualities of
Brain Heart Infusion Agar Using *Bacillus Subtilis* Spores and *Candida*
Krusei as Indicator Organisms
March 9, 1978

903 Supplemental Assay Method to Test for Preservative Interference with
Sterility Tests
April 15, 1992

904 Supplemental Assay Method to Test for Bactericidal Activity of Diluents
Used with Live Bacterial Vaccines
May 1, 1989

905 Supplemental Assay Method for Potency of Live Avirulent *Pasteurella*
Haemolytica Vaccine
May 15, 1991

- 906 Supplemental Assay Method for Sterility Testing of Preparations Other Than Live Vaccines
December 16, 1998
- 908 Supplemental Assay Method for Sterility Testing of Live Viral Vaccines
April 21, 1999
- 909 Supplemental Assay Method for Sterility Testing of Live Viral Vaccines of Chicken Embryo Origin Recommended for Nonparenteral Injection
May 17, 1999 (DRAFT)
- 910 Supplemental Assay Method for Sterility Testing of Live Viral Vaccines and Master Seed Virus Samples
April 21, 1999 (DRAFT)